

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-0474V

CARLA HARGRAVE,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 14, 2025

Glen Howard Sturtevant, Jr., Rawls Law Group (Richmond), Richmond, VA, for Petitioner.

Michael Joseph Lang, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION¹

On January 11, 2021, Carla Hargrave filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the “Vaccine Act”), amending it several months later. Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”), as defined by the Vaccine Injury Table, resulting from influenza (“flu”) and tetanus diphtheria acellular pertussis (“Tdap”) vaccines received on December 4, 2019. Amended Petition at 1. Petitioner also asserts a causation in fact claim, plus the claim that the vaccines may have significantly

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

aggravated some unidentified “underlying immunologic, neurologic, or genetic disorder,” causing the same SIRVA-like symptoms. *Id.*

For the reasons discussed below, I find that Petitioner has not established by a preponderance of the evidence that she is entitled to compensation – under any version of claim that could be articulated based on the record facts. The case is therefore dismissed.

I. Relevant Procedural History

After the case was activated, Petitioner was directed to file additional evidence concerning the onset and cause of her condition, as well as a vaccine administration record (ECF No. 27). Petitioner thereafter filed Exhibits 11 and 12, vaccination records and a supplemental affidavit (ECF No. 31).

Respondent subsequently filed a Rule 4(c) Report, asserting that this case is not appropriate for compensation (ECF No. 36). I then directed Petitioner to show cause why the Petition should not be dismissed (ECF No. 37), and Petitioner filed a response (ECF No. 40). The matter of whether the Petition should be dismissed is now ripe for resolution.

II. Relevant Factual History

A. Medical Records

On December 4, 2019, Petitioner received flu and Tdap vaccines in her left deltoid, at her place of employment. Ex. 12 at 1-2, 4. There is no evidence of any immediate vaccination reaction, or close-in-time treatment efforts.

Nearly two months later (on February 2, 2020), Petitioner went to the emergency department (“ED”) complaining of left shoulder pain. Ex. 6 at 69. She reported that after a car accident eight years earlier she had been experiencing intermittent left shoulder pain, and that her current episode of left shoulder pain had been present for one week – which would place onset in late January. *Id.* She denied any new injury or trauma related to the onset of her pain. *Id.* This record also states that she thought she slept wrong on her arm the week before, and that her left arm pain occurred only when sleeping for the past seven days. *Id.* at 75. On examination, Petitioner displayed limited range of motion (“ROM”). *Id.* at 70. She was diagnosed with a shoulder sprain and given an intramuscular injection of a non-steroidal anti-inflammatory drug, four prescriptions, and a sling. *Id.* at 70-71.

Ten days later, Petitioner saw Dr. Jesse Martinez to follow up on her ED visit. Ex. 5 at 14. This record documents a left shoulder strain with no known etiology. *Id.* On examination, her left shoulder ROM was “fine.” *Id.* Petitioner was advised to return to care as needed. *Id.* at 15.

Petitioner returned to Dr. Martinez on March 25, 2020 for “rotator cuff, of the left arm” that “[s]tarted about three weeks ago after infection” – meaning her symptoms had begun no sooner than early March. Ex. 5 at 12. On examination, Petitioner displayed slightly limited ROM when raising her left shoulder. *Id.* Petitioner was also depressed, noting that she had “inherited” some kids due to her sister’s recent death. *Id.* She was diagnosed with left shoulder osteoarthritis and advised to use prescribed medications, do ROM exercises, apply heat, rest, and take two weeks off work. *Id.* at 12-13.

On April 10, 2020, Petitioner saw Dr. Martinez again, requesting a letter that would permit her medical leave from work. Ex. 5 at 12. He noted that Petitioner complained of “L shoulder still?” and added that she “had shoulder prob[lem]s admittedly prior to covid but she blames hosp[ital] and inj[ection] she got in left arm???. *Id.* Dr. Martinez assessed her with chronic left shoulder pain. *Id.* He believed that Petitioner was “using the L shoulder to try to stay away from [B]eaumont,” and stated that he could not keep her off work any longer. *Id.* Petitioner explained that she was nervous about working at Beaumont due to COVID risk. *Id.* at 10-11. He told her that any further work notes would need to be obtained from an orthopedist. *Id.*

Two weeks later (April 23, 2020), Petitioner saw Dr. Susan Tam for sharp pain and numbness/tingling in her left arm. Ex. 4 at 19. The pain was reported to have been present “since January 2020 after receiving immunizations in left arm.” *Id.* at 20. Dr. Tam ordered an EMG, discussed physical therapy, and directed Petitioner to follow up in two weeks. *Id.*

Petitioner returned to Dr. Tam on May 11, 2020 for “muscle pain (immobility after receiving immunization) and arm pain” with an acute onset, that had been occurring for two months (which would indicate it began in March 2020). Ex. 4 at 15. The “Impression,” or diagnostic, section of the record indicates that the pain had been present since January 2020. *Id.* at 16.

On June 5, 2020, Petitioner saw Dr. Tam. Ex. 4 at 12. The history section is identical to that of the prior visit, again indicating that her pain had been present for two months, putting onset in April 2020. *Id.* However, the diagnostic, section of the record again indicates that the pain had been present since January 2020. *Id.* at 13.

Petitioner returned to Dr. Tam three weeks later (June 26, 2020). Ex. 4 at 9. The history section is identical to that of the prior visit, again indicating that her pain had been present for two months. *Id.* She was diagnosed with a left shoulder injury, and Dr. Tam noted that it was “possibly SIRVA? Happened just after vaccine was given.” *Id.* Dr. Tam referred Petitioner to physical therapy. *Id.*

The following month (July 27, 2020), Petitioner started physical therapy. Ex. 2 at 59. The record of this therapy states that the onset of her symptoms began on January

3, 2020 – nearly a *month* after vaccination. *Id.* She reported that she had vaccinations when she started working and “had pain afterwards that did not resolve.” *Id.* at 62.

B. Declarations

Petitioner filed five declarations in support of her claim.³ Exs. 1, 7, 8, 9, 11. Petitioner states that she moved to Michigan in July 2019 because her sister was dying, and she wanted to support her support her nieces and nephews. Ex. 7 at 1; Ex. 11 at 1. She began working at Starbucks in a hospital, which required her to receive vaccinations. *Id.*

Following vaccination, Petitioner recalls, her “left shoulder and arm kept going out on me and it was very painful at times.” Ex. 7 at 2. She tried to ignore it in hopes that it would go away, but rather than improving the pain worsened. *Id.* She tried to wait for her health insurance to be effective. *Id.* She adds that it “took a while to actually pinpoint that my symptoms were coming from my vaccine.” *Id.* For the first seven months after vaccination, she felt sharp pains as if someone was giving her a shot at the vaccination situs. *Id.* at 2.

Petitioner further states she was considered high risk for COVID and thus waited “until the pain was unbearable before seeking treatment.” Ex. 11 at 1. At the time, she was also helping her sister’s children adjust after her sister’s death in August. *Id.* In addition, and contrary to the February 2020 ED record (Ex. 6 at 69), Petitioner maintains that she was *not* in a motor vehicle accident eight years earlier that resulted in left shoulder pain. Ex. 11 at 1. Nor (again contrary to a record (Ex. 6 at 75)) did she ever relate her shoulder pain to sleeping wrong. *Id.*

Petitioner had been a caretaker to Mac McClendon for ten years, assisting him with bathing and daily activities. Ex. 7 at 2. However, she is no longer able to do this because she herself now needs assistance. *Id.*

Mr. McClendon submitted a declaration dated July 31, 2021. Ex. 8. He states that Petitioner lives with him and has been his caretaker for about ten years. *Id.* at 1. But she has not been able to help him get in and out of the tub “[s]ince her vaccination,” as she now needs help with this. *Id.* He has noticed her asking her son to close her car door because she cannot pull the door closed with her left arm. *Id.* He has observed that Petitioner is depressed and feels worthless because she is limited in her daily activities. *Id.* He does not provide further details about the timeframe in which he has observed these effects or how he is able to recall that Petitioner could not help him since her vaccination, making his statements less persuasive given that his declaration is dated over a year and a half later.

³ Although Petitioner labeled these submissions as affidavits, they are not notarized. Nonetheless, they are acceptable as declarations because they comply with the requirements of 28 U.S.C. § 1746.

Sharee Dooley is a friend who has known Petitioner for 25 years. Ex. 9 at 1. She helps Petitioner with chores a few days a week because Petitioner is unable to use her left arm. *Id.* She has witnessed Petitioner “having pain in her left arm and not being able to lift her arm at all.” *Id.* She has also witnessed Petitioner “holding a cup or something of the sort and dropping it due to pain and lack of strength.” *Id.* She does not state when she began helping Petitioner or when she made these observations. Ms. Dooley adds that she “never [knew Ms. Hargrave] to have this problem with her arm until she went to the doctor to get a mandatory physical to get a job at Starbucks.” *Id.*

III. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must preponderantly demonstrate all matters required under Section 11(c)(1), including the factual circumstances surrounding his or her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the

time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation (“QAI”) are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

IV. Parties' Arguments

Respondent argues that Petitioner has not established that her pain began within 48 hours of vaccination, as required for a Table SIRVA claim, noting that reports of onset recorded in contemporaneous medical records are inconsistent and thus unreliable. Respondent's Rule 4(c) Report, filed July 21, 2023, at *5-6 (ECF No. 36) ("Rule 4 Report"). Thus, at her first post-vaccination medical visit (occurring two months after vaccination), Petitioner reported intermittent pain since a motor vehicle accident eight years earlier that had returned and been present "for 1 week." Rule 4 Report at *5 (citing Ex. 6 at 69). At an appointment ten days later, Petitioner did not mention the cause or onset of her pain. *Id.* (citing Ex. 6 at 14). And the following month, Petitioner told Dr. Martinez that her pain "[s]tarted about three weeks ago after infection[sic]" – placing onset in early March 2020. *Id.* (citing Ex. 5 at 12).

Respondent emphasizes that it was only in April 2020 – four months after vaccination, and when Petitioner sought to use her shoulder pain as a basis for not returning to her job – that Petitioner first attributed her pain to vaccination. Rule 4 Report at *5-6. Petitioner thereafter told Dr. Tam that her symptoms had been occurring "for months" and "since January 2020 after receiving immunizations" – even though her vaccinations were administered in December 2019. *Id.* (citing Ex. 4 at 20). And in June 2020, Dr. Tam documented left shoulder pain that had been "occurring for 2 months" – placing onset in late April 2020. *Id.* (citing Ex. 4 at 10). Respondent adds that Petitioner has not met the significant aggravation standard set forth in *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009). *Id.* at *6-8.

Petitioner responds that she has identified evidence supporting a finding that she suffered SIRVA symptoms within 48 hours of vaccination. Petitioner's Response to Order to Show Cause, filed Jan. 18, 2024, at *1 (ECF No. 40) ("Pet."). In support of her argument, Petitioner states that she claimed in her declaration that her pain began "almost immediately" after vaccination. Pet. at *2 (citing Ex. 7 at 2). (Review of her declarations, however, reveal that they do *not* so state, instead more generally noting pain "[f]ollowing" vaccination. Ex. 7 at 2; Ex. 11 at 2). Although Petitioner did not seek medical care immediately, she states this was due to stress and the demands of her life, that she only had mild pain initially, and that she did not have health insurance. *Id.*

Petitioner argues that her delay in seeking medical treatment is similar to that in *Graczyk v. Sec'y of Health & Human Servs.*, No. 21-0376V, 2023 WL 4573868 (Fed. Cl. Spec. Mstr. June 16, 2023), where a claimant also did not seek care until two months after vaccination. Pet. at *1-2. She emphasizes my statement in *Graczyk* that Respondent's arguments "seem to demand an absolute consistency within a Petitioner's medical records that the Act does not require." *Id.* (citing *Graczyk*, 2023 WL 4573868, at *15).

Although a medical record in April 2020 stated that Petitioner's pain had been occurring "for months," Petitioner argues that later references at the same medical center repeat the same comment, simply adding "2" after the word "months." Pet. at *2-3. Petitioner argues that this "should not be considered to reset the clock on when Petitioner claimed to first experience shoulder pain." *Id.* Acknowledging that the term "months" is vague, Petitioner nonetheless emphasizes that the April appointment was "only four and a half months after the vaccination," and argues that the failure of the medical record to accurately record the number of months her pain had been present "should not be held against her." *Id.* at *3.

Petitioner maintains "[g]iven the evidence that Petitioner suffered pain immediately after the vaccine . . . the vaccination is the most likely cause of the injury." Pet. at *3. She does not clarify what evidence of immediate pain she refers to.

Petitioner also asserts that there is "no evidence of an alternative cause" – disregarding the medical record evidence of *two* possible alternative causes, a motor vehicle accident years prior and sleeping on her shoulder. Pet. at *3. Petitioner adds that the medical records contain references pointing to the vaccination as a "likely cause," citing a primary care record stating "possibly SIRVA? Happened just after vaccine was given." *Id.* (citing Ex. 4 at 8). Petitioner concludes that she believes there is sufficient evidence that vaccination caused pain within 48 hours and that vaccination is the most likely cause. *Id.* at *3-4. Petitioner's show cause response does not address the viability of a causation in fact or significant aggravation claim.

Analysis

Petitioner has not preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination – or within *any* timeframe from which vaccine causation could plausibly be found. Petitioner therefore cannot succeed on any form of claim, Table or causation-in-fact.

The evidence as to the onset of Ms. Hargrave's shoulder pain is admittedly inconsistent, but *not* corroborative of a 48-hour onset, as required for a Table SIRVA. When she first presented for medical treatment two months after vaccination, she reported that her pain had been present for *one week* – which would place onset in late January 2020, 53 days after vaccination. Ex. 6 at 69. Thereafter, she reported on March 25, 2020 that her pain started three weeks earlier – which would put onset in early March 2020. Ex. 5 at 12. Later records suggest that her pain began in January (Ex. 4 at 13, 16, 20), March (Ex. 4 at 15), or April of 2020 (Ex. 4 at 9-13).

The only medical records that could conceivably suggest that the onset of her shoulder pain was closer in time to vaccination are from six to seven months after vaccination, when she reported that her injury happened “just after vaccine was given” (Ex. 4 at 9), and that she had vaccines and “had pain afterwards” (Ex. 2 at 62). But these onset references are non-specific, and less contemporaneous to the events as well (meaning they should be given less weight). See *Bodak v. Sec'y of Health & Human Servs.*, No. 19-2019V, 2022 WL 6956889, at *5 (Fed. Cl. Spec. Mstr. Sept. 8, 2022) (finding onset was not within 48 hours where medical records closer in time to vaccination were inconsistent as to onset, and the only records supporting immediate onset were later in time, six and nine months after vaccination).

I also find that Petitioner’s testimonial evidence is unsupportive of a finding that her shoulder pain began within 48 hours of vaccination. While she states that her pain began “[f]ollowing the vaccinations (Ex. 7 at 2), she does not say *how long* thereafter it began. Other witnesses are similarly nonspecific as to pain onset. Mr. McClendon, for example, states that Ms. Hargrave has not been able to help him with bathing “[s]ince her vaccination.” Ex. 8 at 1. But he does not specify how long after vaccination her limitations began. And his declaration was signed in July 2021, nearly 20 months after vaccination, and without specific information about when he saw her, what he observed, and how he can recall these specifics after this lengthy time, his statements are not sufficient to overcome the medical record evidence overwhelmingly placing onset much later. Additionally, while he states that Petitioner cannot help him with bathing because she now needs such help herself, it is not clear whether this is due to her shoulder injury.

Ms. Dooley asserts that she never knew Ms. Hargrave to have this problem with her arm until she had a physical for her job. Ex. 9 at 1. However, this nonspecific statement does not support a finding that the onset of Petitioner’s shoulder pain occurred within 48 hours of vaccination.

Petitioner’s reliance on *Graczyk* is misplaced. Although Ms. Hargrave and the *Graczyk* petitioner both delayed seeking care for two months after vaccination, the remaining facts are not comparable. In *Graczyk*, when the petitioner *first sought care* for her shoulder pain, she related her pain to vaccination. *Graczyk*, 2023 WL 4573868, at *3. And thereafter, that petitioner’s medical records consistently documented pain since vaccination and related the onset of her symptoms to her vaccination, noting the date of vaccination (with the exception of a single record which Respondent did not rely on in contesting entitlement). *Id.* at *3-4, 6.

Here, by contrast, the medical records are wholly inconsistent about when Petitioner’s shoulder pain began, and overwhelmingly place onset no sooner than one month after vaccination. The strongest record suggesting that Petitioner’s pain began closer in time is a single notation (from six months after vaccination) stating that her injury occurred “just after” vaccination, but without clarifying *how long* after. In the context of the

lack of supporting testimonial evidence, and the fact that more contemporaneous records suggest onset was much *later* than 48 hours after vaccination, I find that a preponderance of the evidence supports a finding that the onset of Petitioner's shoulder pain was likely *far* later than 48 hours after vaccination – too late for a Table claim, or even off-Table claim for that matter. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). I simply cannot conclude on this record that there was a medically acceptable timeframe relationship between Petitioner's vaccination and onset of her injury (whatever it might be).

Petitioner also cannot prevail on a significant aggravation claim. She has not identified a pre-existing condition that could be deemed to have been significantly aggravated by the vaccinations. And the onset problems that defeat her Table and off Table claims also mean that she cannot preponderantly establish a proximate temporal relationship between vaccination and any significant aggravation sufficient to prevail on a significant aggravation claim. *Loving*, 86 Fed. Cl. at 144.

Conclusion

Petitioner has failed to preponderantly establish that her injury meets the requirements for a Table SIRVA, an off Table claim, or a significant aggravation claim. Accordingly, this case is DISMISSED for insufficient evidence. The Clerk of Court shall enter judgment accordingly.⁴

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁴ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.